IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

PRECISION THERAPEUTICS, Plaintiff, v. KATHLEEN SEBELIUS, Secretary of the United States Department of Health and Human Services, Defendant.	))))))))))	Civil Action No. 09-451 Judge Joy Flowers Conti Magistrate Judge Lisa Pupo Lenihan

REPORT AND RECOMMENDATION

I. Recommendation

It is respectfully recommended that the Defendant's Motion for Summary Judgement be denied, that the Plaintiff's Motion for Summary Judgment be granted except as to its request for costs and fees, and that the decisions of the Secretary of the United States Department of Health and Human Services ("DHHS") be remanded to the Administrative Law Judges (the "ALJs"), as more fully set forth below.

More particularly, remand is recommended in light of the ALJs' (a) failure to weigh or address their rejection of contrary probative evidence regarding the patient benefit(s) of Precision Therapeutics, Inc.'s ("PTI") chemotherapy assay laboratory test, and/or (b) reliance on unsubstantiated assumptions integral to conclusions that the assay is not “reasonable and necessary”, and therefore unentitled to Medicare reimbursement, under Part B of the Medicare

program. See Title XVIII of the Social Security Act (the "Act") and the regulations of the Centers for Medicare and Medicaid Services ("CMS") (formerly the Health Care Financing Administration ("HCFA")).

Because the Report concludes that the Court cannot complete meaningful substantial evidence review at this time, but must remand the decisions for further consideration by the ALJs,[1] it need not now address the myriad other concerns raised in the parties' pleadings.

II. Report

Presently before the Court for disposition are cross motions for summary judgment.

A. Factual and Procedural Background

Precision Therapeutics, Inc. ("Plaintiff" and "PTI"), by its counsel, timely filed a Complaint for review of the Secretary's final determinations denying coverage and reimbursement on behalf of more than 120 individual Pennsylvania Medicare cancer patients for ChemoFx, a chemotherapy assay test. The relevant background information and the history of this matter are as follows:

1. See, *e.g.*, Beckett v. Leavitt, 2008 U.S. Dist. LEXIS 38243 (E.D. Pa. April 14, 2008) (concluding that record failed to provide adequate basis for judicial review and required remand where ALJ failed to explain reasons for rejection of competent contrary evidence); Harzewski v. Chater, 977 F.Supp. 217 (W.D.N.Y. 1997) (holding that ALJ's decision containing "unexplained assumptions and unsupported conclusions" failed to "provide the Court with an understandable background for its review"). Cf. Hippensteel v. Sullivan, 1990 WL 300288 (M.D. Pa. Dec. 20, 1990) (reversing ALJ decision based on improper legal standards and unsupported assumptions).

1. Medicare Coverage Determination Overview

The Medicare program is administered by the Department of Health and Human Services, via the Centers for Medicare and Medicaid Services, and includes two types of benefits: hospital

insurance benefits (Medicare Part A) and supplemental medical insurance benefits (Medicare Part B). Section 1832 of the Act sets forth the scope of benefits provided by Part B, which encompasses payment of "medical and other health services", including diagnostic laboratory and other tests.

Section 1862 of the Act provides a listing of services and supplies excluded from coverage under the Medicare program, and § 1862(a)(1)(A) provides an exclusion from coverage for any item or service which is "not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." See 42 CF.R. 411. Services so excluded may, however, still be covered under § 1879(a) where the appellant/beneficiaries neither knew or could reasonably be expected to know that the services would not be payable on the basis of published notices or knowledge of acceptable standards of practice by the local medical community. See 42 C.F.R. 411.406.

The Secretary contracts with regional/local "carriers" or "contractors" to process claims review and payments, and issues instructions through various manuals and memoranda. The provisions of the Secretary's carriers' manuals, program memoranda, transmittals and carrier publications are not binding on the ALJs, but may be accorded significant weight because they clarify and explain the agency's interpretation of its regulations. National Coverage

Determinations are listed in a Coverage Issues Manual ("CIM") and, like the provisions of the Act and the accompanying regulations, see 40 C.F.R. Part 400 *et seq*, are binding on the ALJs.

Medicare carriers and intermediaries make the initial determination on medical necessity when Medicare claims are processed. See § 1842(a)(1)(A), 42 C.F.R. § 421.1 *et seq.* ALJs within the Office of Medicare Hearings and Appeals ("OMHA") issue the final decisions of the Secretary, except for decisions selected for review by the Medicare Appeals Council (the "MAC"). See Decision of ALJ Steele at 3. The provider of health care services or supplies has the initial burden of proving its claim in Medicare cases.

2. History of Chemotherapy Assays

The intended purpose of the PTI chemotherapy assay is to assist physicians/oncologists in selecting among chemotherapy drugs for their patients with cancer, by providing a means to identify individual patients' responsiveness to alternative drugs and dosage levels, thus avoiding toxic and expensive courses of ineffective/less effective chemotherapy and maximizing the patient's benefit from the chemotherapy treatments undergone. A patient's course of treatment has traditionally been based largely on the available empirical evidence, *i.e.*, on regimen response rates to chemotherapy drugs/drug combinations across a broad population, referred to as the "established protocol". And an established or clinical protocol's effectiveness for an individual patient has been determined by "trial and error", *i.e.*, the protocol is tried, generally over a period of some weeks, and the patient's degree of responsiveness is evaluated. If the patient's response is poor, another chemotherapy protocol may then be tried, and so on.

The number of potentially effective treatment alternatives (both drugs and combinations of drugs) available to oncologists in treating various forms of cancer has been proliferating, and clinically/histologically similar tumors do not always respond the same way to the same

chemotherapy drugs. Thus, although the assays are not intended to supplant the traditional "method of selecting chemotherapy based on population response rates and physician judgment", they are "tests that can be used to enhance the probability of selecting the most effective treatment for the individual patient when a number of equivalent options are available, similar to the use of estrogen receptor expression and antiestrogen therapy in breast cancer." Gallion *et al.*, "Progression-free Interval in Ovarian Cancer and Predictive Value of an *Ex Vivo* Chemoresponse Assay", 16 Int. J. Gynecol. Cancer 194 (2006) (the "IJGC Study").

In 1982, as chemotherapy assays were evolving, a national coverage determination was issued that precluded Medicare coverage for chemotherapy testing that employed stem cells. See Medicare Coverage Issues Manual § 50-41 ("Human Tumor Stem Cell Drug Sensitivity Assays"). In the 1990's, a drug-resistance assay (the "EDR assay") was developed - following an National Cancer Institute research grant - by Oncotech, Inc., in California.. This next-generation assay utilizes the patient's fresh, live tumor cells; does not employ reducing cancer cells to a single stem cell; and exposes the patient's tissue to massive levels of chemotherapy drugs to determine which are least effective *in vitro (*in a test tube). Clinical studies established the assay's high correlation/predictability for patient "resistance" (*i.e.*, unresponsiveness to that chemotherapy drug). See, *e.g.*, Drs. David H. Kern and Larry M. Weisenthal, "Highly Specific Prediction of Antineoplastic Drug Resistance With an In Vitro Assay Using Suprapharmacologic Drug Exposures", Journal of National Cancer Institute, Vol. 82, pp. 582-588 (1990) (indicating high predictive accuracy). Despite extended periods of "negotiated rulemaking" and meetings of the DHHS' Technology Advisory Committee, Oncology and Anatomic Pathology Workgroup,

and Laboratory and Diagnostic Services Panel in the late 1990s, no national coverage policy determination regarding non-stem cell chemotherapy assays was ever made. See A.R. at 1589-90.[2] From 2000 on, however, the California carrier/contractor has provided coverage for EDR assays for chronic lymphocytic leukemia and solid tumors. See, *e.g.*, A.R. at 1599.

PTI is a federally-certified independent diagnostic testing laboratory located in Pennsylvania. The PTI-developed assay ("ChemoFx") exposes patient's tissue to varying doses of chemotherapy drugs and reports *both* resistance (*i.e.*, the drugs which are *least* effective against patient's cancer *in vitro*) and, with reduced predictability, sensitivity (those which are *most* effective).[3] A treating physician/oncologist directs that samples be obtained from the patient's tumor during biopsy and a "tumor requisition form" includes the patient's diagnosis and certification that the assay is medically necessary for treatment. See PTI's Memorandum of Law in Support of Motion for Summary Judgment ("PTI's MLSMSJ") at 3.

As early as July, 2000, the Pennsylvania Carrier, HGSAdministrators ("HGSA"), concluded that it could no longer continue to deny coverage of PTI's assay as experimental (because all of the oncology members "ha[d] said that human tumor sensitivity testing is no

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2. See also A.R. 7263 (Notes of Panel Meeting, recording "general feeling among panelists that [assays] seemed to be cost effective, and that they should be added to the tools that a physician had available"); id. at 7264 (noting that "motion that there was not sufficient scientific evidence to demonstrate a clinical utility in selecting appropriate therapy" was voted down 8 to 1).

3. Cf. A.R. at 1592 (May 30, 2003 Decision of ALJ Cummings noting, in course of 44 page consideration and approval of medical necessity of ChemoFx assay, "the reciprocal natures of resistance and sensitivity" (*i.e.*, the drugs to which the patient's tumor are least unresponsive (or "resistant") are, *ipso facto*, those to which it is most responsive (or "sensitive")) and that the ChemoFx provides more refined tissue response information).

longer experimental"), but that it "would like to deny" claims on this "expensive test which seem[ed] to be gaining in popularity . . . based on unproven clinical efficacy." While acknowledging that this might appear a minor differentiation, HGSA proposed coverage denial because the testing was "not standard medical practice and . . . most physicians would not deviate from standard treatment based on the [test] results". See A.R. at 1373 (Letter of Carrier Medical

Director, Andrew Bloschichak, M.D.).[4] In September, 2004, HGSA began to provide Medicare reimbursement for a setup/"culture" fee for PTI assay claims, but continued to deny coverage for the specific drug tests. Some time thereafter, the contractor also began to approve coverage of PTI assays for patients with gynecological tumors, but did not issue a local coverage determination (referred to as an "LCD"). See Defendant's MSJ at 27 (citing A.R. at 136).

3. ALJ Jones' June 2, 2006 Decision

The claims at issue in this decision were submitted for Medicare reimbursement to HGSA, a Pennsylvania carrier/contractor, between June 2002 and August 2004. HGSA initially denied more than 130 of these claims (another CMS contractor denied two additional claims, which were consolidated), and PTI requested a hearing before an ALJ in the Office of Medicare Hearings and Appeals, a component of the Office of the Secretary of DHHS. ALJ Jones upheld 79 denials, but reversed 54. See A.R. 131-53.

In his summation of PTI's evidence, ALJ Jones: (a) acknowledged that "[m]any physicians and hospitals order the [assay] and hundreds of health insurers throughout the country

4. This proposed basis for denial was apparently founded on the solicitation, by an HGSA registered nurse, of three (3) survey responses - one written and two oral - from Carrier-affiliated physicians whose qualifications have not been disclosed. See discussion *infra*.

pay for these tests"; (b) noted that the "Tumor Requisition Forms" supporting each claim are signed by physicians and include a certification that the assay is "medically necessary to manage the patient's condition"; and (c) observed that PTI provided three (3) ALJ decisions authorizing reimbursement for the EDR assay, and two (2) decisions by an ALJ (one on May 30, 2003 and another on July 18, 2005) concluding that the PTI assay was covered for the same reasons. Decision at 3-5.[5] ALJ Jones also noted the January 2006 peer-review article published in the International Journal of Gynecological Cancer (the IGJC Study), concluding that assay tests on more than 300 patients over 5 years "resulted in a 'statistically significant' increase in the patients' progression-free interval when measured against the mean response achieved by chemotherapy in general", and that while the assay had greater response-predictability for resistance than sensitivity, the "relatively small number of patients who were treated exclusively with 'sensitive drugs' experienced progression-free intervals two to three times longer than the average chemotherapy response."[6] He further noted that although patients "most commonly" received the standard chemotherapy protocol, the increase in progression-free interval was "most noticeable in the group of [recurrent cancer] patients whose treatment consisted of [assay] tested [sensitive] drugs alone", and that other medical journal articles (including a September, 2004 American Society of Clinical Oncology ("ASCO") publication (the "ASCO Assessment")) concluded that "treatment with drugs selected by [assays] had the most value in avoiding ineffective treatments

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5. These are the decisions of ALJ Cummings, discussed *infra*. Cf. A.R. at 2455-2468 (ALJ Cummings' second decision, reversing denial by HGSA of over 500 claims for ChemoFx assay).

6. The "progression free interval" is the period of time before the tumor recurs or progresses. See, *e.g.*, A.R. at 748.

for certain types of recurrent cancers, but did not increase patient survival" and recommended further clinical trials.[7] Decision at 5-6. Finally, he cited to an oncology textbook stating that "the current state of chemoresponse testing" indicated that although the promise of a sensitivity assay had not been met, there was value in resistance identification. Decision at 8 (quoting DeVita, Cancer: Principles & Practice in Oncology, 5th Ed. (1997)).[8]

In his analysis, ALJ Jones concludes that assays to plan "*bona fide* chemotherapy options for *recurrent or relapsing* cancers will generally be reasonable and necessary", given their "reliability . . . in identifying 'resistant' drugs", but that "the use of [the PTI assay] to identify the most effective chemotherapy agents to treat the *initial or primary* appearance of tumors is not 'reasonable and necessary'" because "a physician treating a patient for the initial occurrence of a gynecological, breast or colon cancer would be unlikely to deviate from a chemotherapy regimen well-established by clinical trials based solely on the results of [the] assay" because it would, "[a]mong other things, . . . expose the physician" to liability for failing to follow the standard of

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7. The ASCO Assessment was made in cooperation with Blue Cross Blue Shield (BCBS) and the HCFA, and in conjunction with a Technology Assessment undertaken by the BCBS Association and published that same month in the Journal of Clinical Oncology. See A.R. at 7867. Cf. A.R. at 7934-35 (Affidavit of Gerald Rogan, M.D., a Medicare Consultant formerly based in California (explaining that BCBSA Technology Assessments are based on more stringent criteria than those used for Medicare coverage determinations, and that Medicare covers many treatments for which BCBSA assessments found insufficient evidence); cf. also Plaintiff's Reply In Support at 7 (observing that none of the 12 studies discussed by ASCO involved ChemoFx).

8. Cf. A.R. at 7242 (excerpt from Dr. DeVita's 1997 text, indicating that "because the accuracy of these tests to predict patient resistance usually exceeds their accuracy to predict patient response, these assays may be better described as in vitro drug-response assays rather than chemosensitivity assays").

care. Id. at 8 (emphasis in original). See also id. at 9 (observing that although physicians indicate that assay results are a factor in planning chemotherapy and "the value of chemoresponse assays is 'intuitively obvious'", they do not indicate "that assay results warrant conclusive weight in initial treatment settings"; and concluding that a physician's "desire for maximum information" does not bring a service within the "reasonable and necessary" standard); but compare id. (noting that the "side effects factor" is also important in selecting among chemotherapy alternatives).

ALJ Jones thus concluded that the assay was reasonable and necessary only when planning chemotherapy options for patients with recurrent or relapsing cancers, or under the unique circumstances of two individual beneficiaries: one whose "ability to tolerate chemotherapy [was] so limited it dominate[d] any decision-making based upon clinical trial protocols" and the other "where no established . . . protocol exist[ed]" for a rare carcinoma. Id.

PTI requested review by the Medicare Appeals Council ("MAC") of the 79 claims for which ALJ Jones denied coverage. On February 27, 2009, the MAC denied the request for review, concluding that the Decision was supported by substantial evidence.

4. ALJ Steele's Decisions

The claims at issue in these decisions were submitted for Medicare reimbursement to HGSA between February 2004 and September 2005, and 45 claims were initially denied. On appeal, they were divided into two groups which were both assigned to ALJ Steele, who upheld the denials by substantially similar decisions of January 5th and January 9th, 2007. See A.R. 5322-5334 and 5698-5710.

In his comparatively succinct denials, ALJ Steele relied on the ASCO Assessment,[9] the July, 2000 letter of HGSA Director Bloschinchak stating that "use of the test is not standard medical practice and most physicians would not deviate from standard treatment based on the results", and on the HGSA's three physician questionnaire responses opining that the assay is not medically necessary. In concluding that the assay was not "efficacious" (and therefore not reasonable and necessary), because (a) "there is no established clinical data which points to the physician's likelihood to change chemotherapy agents absent the assay test results" and (b) "[t]he establishment of the [assay] in mainstream medicine has not been established or proven more reliable than empirical therapy",[10] ALJ Steele minimally noted the other peer-reviewed publications,[11] and did not address PTI's significant expert/clinical practice evidence of the assay's utility and general medical acceptance.

PTI requested review by the MAC, which denied the request on February 17, 2009, concluding that the Decision was supported by substantial evidence.

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9. ALJ Steele cites, in particular, the ASCO Assessment's statement that "in the absence of [assays], the clinical efficacy of different chemotherapy regimens is very similar." Decision at 8. Yet the text of the ASCO Assessment indicates this comes from its discussion of the increased potential benefit/importance of assays given recent proliferation of chemotherapy alternatives. See A.R. 7872 (ASCO Assessment, noting that "[w]hen few chemotherapeutic options are available and the array of choices is limited, the potential impact of [assays] is also circumscribed", that "[o]ver the past decade, a large number of new therapeutic agents . . . have been . . . approved and the array of choices facing oncologists has grown ever more complex" and that, "in the absence of [assays], the clinical efficacy of different chemotherapy regimens is very similar"). Cf. *supra* at 4.

10. See Decision at 7, 9

11. See Decision at 8 (concluding that because "the evidence presented indicates the *in vitro* testing . . . on a solid tumor biopsy does in fact reveal which chemotherapy drugs the tumor responds to" but "the clinical trails . . . relied upon do not demonstrate that the use of the . . . assay test results alters the physician's determination of which chemotherapy agent will be used", its efficacy is not established).

B. "Substantial Evidence" Standard of Review

Under Section 1869 of the Act, the Secretary has the authority to make determinations with respect to benefits under Parts A and B of the Medicare program, in accordance with its regulations. The Secretary's discretion, while broad, is not boundless, Rather, the determinations

must be supported by substantial evidence and are to reflect consideration of the administrative record as a whole and resolution of factual issues.

"Appellate courts retain a responsibility to scrutinize the entire record and to reverse or remand if the . . . decision is not supported by substantial evidence." Smith v. Califano, 637 F.2d 968, 970 (3d Cir. 1981). See also Motor Vehicle Mfrs. Ass'n of the U.S. v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 32 (1983) (consideration by reviewing court includes whether agency "failed to consider an important aspect of the problem [or] offered an explanation for its decision that runs counter to the evidence").

A generic statement that the ALJ considered all the evidence is insufficient if the decision fails to provide an explanation for the ALJ's rejection of probative evidence to the contrary. See Cotter v. Harris, 642 F.2d 700, 706-07 (3d Cir. 1981) (noting that the ALJ must provide an explanation of the reason why probative evidence that would suggest a contrary disposition was rejected);[12] see also, *e.g.*, Beckett v. Leavitt, *supra* ("[T]o guard against an abuse of discretion by

12. Compare Memorandum in Support of Defendant's Cross Motion for Summary Judgment and in Opposition to Plaintiff's Motion for Summary Judgment (hereafter "Defendant's MSJ") at 12.

the Secretary, the ALJ is required to provide some indication of the evidence which was rejected in arriving at the decision and the reasons therefore, so that a reviewing court can determine whether probative evidence was properly credited or simply ignored.") (citing Cotter); id. (concluding that ALJ acted in "dereliction of his duty to explicitly weigh all evidence"); id. ("Unless the Secretary has analyzed all evidence and has sufficiently explained the weight he has given to obviously probative exhibits, to say that his decision is supported by substantial evidence approaches an abdication of the court's 'duty to scrutinize the record as a whole to determine whether the conclusions reached are rational.'") (citing to Benton v. Bowen, 820 F.2d 85 (3d Cir. 1987), Dobrowolsky v. Califano, 606 F.2d 403 (3d Cir. 1979), Sykes v. Apfel, 228F.3d 259, 266 (3d Cir. 2000)).[13]

Similarly, the Third Circuit has noted that evidence is not substantial "if it is overwhelmed by other evidence . . . or if it really constitutes not evidence but mere conclusion." Kent v. Schweiker, 710 F.2d 110, 114 (3d Cir. 1983). Thus, unsubstantiated assumptions also require remand. See *supra* n. 1.

C. Reasonable and Necessary Standard

There is no more precise statutory or regulatory definition of "medically necessary" than the "reasonable and necessary for the diagnosis or treatment of . . . illness or injury" language of Section 1862(a)(1)(A); see also 42 C.F.R. § 411.15(k). But the basic consideration is often

13. The explication required by an ALJ's obligation to address contrary probative evidence turns, therefore, on the content and not on the size of the administrative record. Cf. Defendant's Memorandum in Support at 17. And the right of the claimant is not only to have "an opportunity to fully develop [its] evidence for . . . consideration", but also to have it considered. Cf. id.

whether the service is generally accepted by the professional community as safe and effective. See, *e.g.*, A.R. at 1603 (observing that in November, 1999, Dr. Bagley, as Director of Coverage at CMS/HCFA advised the MCAC Panel that key concepts behind the "reasonable and necessary" standard are "safety, effectiveness, benefits outweigh the risks, results in improved clinical care, and has value"); id. at 1607, 1602 (observing that Secretary's 1987 published standard of what is "reasonable and necessary" required that "service or procedure be safe, effective, and not experimental") (citing 54 FR 4302, January 30, 1989).[14]

D. Treating Physician Rule

The application of the "treating physician rule", applied in Social Security disability cases, to Medicare cases is unclear. In a published Ruling in 1993 (following decisions of the Second Circuit and Western District of New York suggesting that the rule would or could apply to Medicare cases), the Secretary directed that "no presumptive weight" be assigned to the treating physician's medical opinion as to inpatient hospital or skilled nursing facilities, but declined to provide a definitive answer to applicability of the rule in other Medicare cases. See HCFAR-93-1, May 18, 1993; A.R. 1606 (citing cases).

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14. Cf. Medicare & Medicaid Guide (CCH) ¶ 28,152 (1976); CMS Medicare Intermediary Letters Nos. 77-4 & 77-5 (explaining that services may be denied coverage as "experimental" based on "qualified medical advice that the items and services have not been generally accepted by the professional medical community as effective and proven treatments for the conditions for which they are being used in the particular cases" and that "if the service or treatment is not yet generally accepted, is rarely used, novel or relatively unknown, then authoritative evidence must be obtained to establish it is safe and effective before Medicare may make payment"). This language suggests that a medical community's consensus that a service is no longer "experimental" also indicates that service's "general acceptance" within that community. Cf. *supra* at 6 (noting that all of carrier's oncology members felt sensitivity testing was no longer experimental in 2000).

While it is not clear what weight should be accorded the treating physicians' informed opinions in Part B Medicare cases, it seems apparent that they are entitled to some consideration. See A.R. 1611 (May 30, 2003 Decision of ALJ Cummings, concluding, on this authority, that "[w]hen the Secretary does not establish specific criteria for coverage, but relies only on the 'reasonable and necessary' criteria of the Act, it is appropriate to consider the treating physician's opinion" and that "the Secretary is obligated to presented a reasoned basis for its decision rejecting or giving little weight to the treating physician's opinion and must do so in conformity with the statutory purposes").

E. Analysis

1. Clinical Studies; ALJ Opinions; Treating Physician, and Other Medical Professional Evidence

The Court observes that in proceedings before both ALJ Jones and ALJ Steele, PTI submitted a substantial quantity of documentary and testimonial evidence, including significant evidence of clinical studies, other ALJ opinions, and testimony by/declarations from witnesses with expertise in their fields (including Heads/Chairs/Directors of medical facility oncology departments, oncology professors/academicians, and researchers).[15] One or both ALJs', and the MAC's, treatment of some of this evidence merits discussion:

(a) Clinical Studies

As noted in Plaintiff's MLSMSJ, it provided substantial evidence of peer-review published studies of the high degree of correlation between *in vitro* and clinical/*in vivo* response

15. The Administrative Record in this case is comprised of seventeen (17) copious binders totaling 8,763 pages.

rates, as well as the outcome benefits (defined to include longer progression-free intervals) to patients with initial/primary and recurrent tumors. See generally, Plaintiff's MLSMSJ at 20-21. It also provided a meta-analysis aggregating data from more than 30 published studies involving over 1600 patients and 15 categories of solid tumors. See id. at 22; A.R. at 7247-49. See also Plaintiff's May 27, 2010 Letter Supplement (identifying study evidence of assay utility in Administrative Record). Although ALJ Jones briefly discussed the IJGC Study, he appears to have made unwarranted assumptions therefrom and/or failed to address its implications. See, *e.g.*, *supra* at 7-8 (citing ALJ Jones' Decision, which (a) notes that patients in IJGC study (comprised of initial and recurrent cancer patients) "most commonly" received standard protocol and that study demonstrated progression-free benefits to patients whose oncologists had individualized response information, but (b) concludes that the assay is not reasonable/necessary because a physician would be unlikely to alter an initial standard protocol owing, *e.g.*, to fear of legal liability, and would not rest treatment decisions solely/conclusively on assay results). ALJ Steele engaged in no meaningful discussion of the other studies.

As Plaintiff also notes, the MAC, in declining review, proffered the *post hoc* justification that the IJGC Study need not have been considered because "CMS has stated that studies in which authors have a financial interest in the outcome ' are not sufficient evidence of general acceptance by the medical community.'"[16] This provision of the Medicare Program Integrity Manual (§ 13.7.1) applies to the development of local coverage determinations. Assuming its applicability to individual determinations, the full text of that provisions makes clear that it is

16. As discussed in the parties' pleadings, the nine authors of the IJGC multi-center peer-reviewed study included two individuals affiliated with PTI.. See Plaintiff's Reply Memorandum at 9; Defendant's Reply at 8.

distinguishing "limited case studies *distributed by sponsors* with a financial interest in the outcome" from research studies published in peer-reviewed medical journals. Id. at § 13.7.1. And even if the provision *were* applicable to studies conducted by multiple unaffiliated co-authoring physicians, and published in peer-reviewed journal articles subject to approval by an institutional review board, manual language observing that a sponsor-distributed study is not sufficient evidence, in itself, of general acceptance, does not countermand an ALJ's duty to consider and weigh the probative evidence.[17]

(b) ALJ Opinions

As the parties observe, the Decisions of other ALJs on the same or related issue are of no precedential value. They can, however, be informative in their extensive review of contrary probative evidence provided but not similarly discussed in the decisions *sub judice*. See, *e.g.*, Decisions of ALJ Cummings, *supra*.

(c) Treating Physicians' Certification of Medical Necessity

The opinion of the treating physicians requesting the assay, including, *e.g.*, the Tumor Requisition Form's certification that the assay "is medically necessary to manage the patient's condition", and the implicit indication that those physicians deemed it medically appropriate to utilize the assay's additional, individualized information in the patient's cancer treatment decisions (*i.e.*, that the information *could* alter/affect the course of treatment), were apparently

17. Cf. A.R. at 7894 (Correspondence Response in May, 2005 Journal of Clinical Oncology, in response to letters critical of the ASCO/BCBS Assessments, acknowledging that ASCO/BCBS technological assessments (unlike, *e.g.*, articles such as the IJGC Study) "do not undergo the regular peer review process").

given no weight by the ALJs. Nor did the ALJs address the apparent tension between the treating

physicians' request and certification of the assay for these patients, and the ALJs' assumption that the assay was inefficacious/ without utility (*i.e.*, that it could/would not impact the physicians' treatment decisions). See discussion *infra*.[18]

(d) Testimony of Former CMS/HFCA Director; Other Oncologist/Medical Professional Evidence

As noted above, PTI submitted extensive physician evidence, including the detailed December, 2002 Declaration of Grant P. Bagley, M.D., J.D. Dr. Bagley, now a partner at the Washington, D.C. firm of Arnold & Porter, was employed by CMS/HFCA for several years, and served as Director of the Coverage and Analysis Group in the Office of Clinical Standards and Quality from 1997 to 1999.[19] During that time, chemotherapy assays were reviewed by the

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18. Cf. A.R. at 1603 (Director of Coverage at CMS/HCFA advised that key concepts of "reasonable and necessary" were "results in improved clinical care, and has value").

19. Other written testimony submitted by PTI included, *e.g.*, that of: Sally Hosford, M.D. (Dr. Hosford holds her B.S. and M.S. in Biological Sciences from Stanford University, and serves as Asst. Director of Gynecologic Oncology in Atlanta. She explains that she utilizes the assay for patients with (1) failed chemotherapy, (2) rapid disease progression, or (3) a variety of possible regimens**;** that the assays are safe and effective; and that if a drug was shown to be resistant by the assay, she would avoid giving it to the patient) see A.R. at 1176; Bernd-Uwe Sevin, M.D., Ph.D., Chair of the Dept. of Obstetrics and Gynecology at the Mayo Clinic in Jacksonville (Dr. Sevin states that he uses the assay as the standard of care in his practice; that its utility in ovarian and breast cancer treatment is confirmed; and that "the current generation of chemoresponse assays are medically necessary") see A.R. at 1183.; Mark McCarthy, M.D. (Dr. McCarthy is an Arizona oncologist who writes that the assay is "safe and effective", and he utilizes it as a factor to assist in management of "breast, lung and ovarian tumors, because multiple chemotherapy drugs are potentially useful" and the assays "affect [his] treatment recommendations"); see A.R. at 1214**;** Virginia J. Stark-Vance, M.D. (Dr. Stark-Vance is a Texas oncologist specializing in brain tumors, who followed a residency at Georgetown University Hospital with a fellowship in Medical Oncology at the National Cancer Institute, and who has authored numerous peer-reviewed articles on cancer management. She writes that the assays are "clinically proven", "safe and effective", and she uses the ChemoFx assay in practice to assist in determining effective treatment options for initial/primary brain tumor and recurrent common cancer patients) (continued...)

Technology Advisory Committee, subject to Negotiated Rulemaking, and reviewed by the Medicare Coverage Advisory Committee. See A.R. at 1587-88. Dr. Bagley's testimony was that the ChemoFx assay: "provides a drug response profile that is clinically useful to help determine the appropriate course of treatment for an individual patient", "is not limited to drug sensitivity testing", "is reasonable and necessary", "helps identify the chemotherapeutic regimen with the greatest likelihood of success for combating an individual patient's tumor [and] helps oncologists identify and avoid highly toxic treatments that offer little likelihood of benefit", and "offers tangible benefits to patients." He also observes that: "[s]ubstantial scientific research has validated the clinical value of the ChemoFx assay"; in determining coverage, local "[c]ontractors are to consider not only scientific evidence but also expert opinion and standards of practice in the community" and that "[g]iven the recent expansion of chemotherapy options, quantitative information . . . from chemoresponse tests helps a physician weigh competing

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19. (...continued)
A.R. at 689-91; James W. Orr, Jr., M.D. (Director of Florida Gynecologic Oncology, writing that the assays are accepted and used in the gynecologic oncology community, "not to dictate therapy, but . . . as an important piece of data to help guide the physician", that he uses the assays in primary and recurrent gynecologic malignancies and "anytime that I am considering chemotherapy as a treatment option"; that ChemoFx is a "newer generation test" that offers advantages over the earlier EDR assay; and that its clinical utility as a diagnostic test to identify both drug resistance and sensitivity is clearly demonstrated) see A.R. at 769-771; Leslie DeMars, M.D. (explaining that use of assay guided chemotherapy at Dartmouth-Hitchcock Medical Center resulted in more than doubling of response rate); Ronald B. Herberman, M.D. (Former Head of Cellular and Tumor Immunology Section, National Institute of Health, and Director of University of Pittsburgh Cancer Institute, who attests that he is "aware of many treating oncologists who strongly believe these tests are a valuable tool in their management of patients" and advance the physician's ability to select the most appropriate drugs, and that "compared with the expected response rates . . . study after study has shown positive results for those who have assay-guided therapy", which "improves the results of clinical study derived medicine") see A.R. at 8096.

chemotherapy options . . . and select the most appropriate regimen . . . ." See A.R. at 1231-1247.

PTI's medical specialists' testimony, including that of Former Director Bagley, was not addressed by ALJ Jones. Nor was it addressed by ALJ Steele, who does give express weight to the three physician opinions solicited by HGSA. See Decision at 8. The Administrative Record indicates the history of the HGSA physician opinions relied upon by ALJ Steele to be as follows: In March, 2000, a Nurse Medical Policy Analyst (Anita Youtz, R.N.) sent a survey to three (3) members of the Carrier Advisory Committee (Eamonn Boyle, M.D.; Raymond Vivacqua, M.D.; and David Chernicoff, D.O.). Only Dr. Chernicoff replied in writing; his survey response was neither signed nor dated. The response indicated the use of chemosensitivity testing was not beyond the investigational stage, not considered a locally acceptable standard of practice, and not of proven efficacy.[20] The nurses' notes of conversations with the other two physicians on April 13, 2000 were memorialized in memoranda stating that (1) Dr. Vivacqua said he does not use chemosensitivity assays and as far as he knows the physicians who do use the tests "do not stop conventional chemotherapy based on the test results", but look to them when conventional medications have failed;[21] and (2) Dr. Boyle

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20. See A.R. at 7217 (Survey response, indicating that "in vitro sensitivity does not necessarily correlate [with] in vivo response" and "[a]t present, these tests are not accurate enough to replace clinical data" and "are expensive").

21. A.R. at 7221. Compare, *e.g.*, A.R. at 7276-77 (Transcript of testimony before MCAC Panel of Dr. Richard Nalick, clinical professor oncologist at U.S.C. School of Medicine and Los Angeles oncologist, describing how after seeing effectiveness of assays with hundreds of patients who failed initial clinical protocols, he began to use assay testing "up front" , and if a test showed extreme drug resistance he "stopped using it" and picked the best candidates from the remaining drugs, "keeping in mind toxicity and their track record in oncology"); id. (also observing that testing has directed combinations that "aren't usually used" but can have "synergy" and be effective, and that he treats patients with the "safest combination that looks

(continued...)

reported the tests were not "mainstream medicine", "rarely change the patient's treatment" and "'Medicare money' would be better spent elsewhere at this time".[22] No *curriculum vitae* for these physicians are of record. Nor were they provided to a prior ALJ who expressly requested them from HGSA (the carrier's attorney advised they could not be obtained). See A.R. at 1598-99; see generally A.R These survey responses were apparently solicited in the course of HGSA's formulation of the new basis on which it wished to continue to deny coverage. See *supra* at 6 (citing to Letter of HGSA's Medical Director, Dr. Bloschichak).[23]

The Court notes that the MAC's conclusion that an ALJ could properly disregard the multiple written declarations (accompanied by *curriculum vitae)* proffered by Plaintiff because, as testimonials, they were not entitled to any weight under provisions of CMS Ruling 93-1 appears at odds with its implicit sanction of ALJ Steele's express weighting of, *e.g.*, a nurse's notes of telephone conversations with two physicians of unidentified qualification.[24]

2. Application of Reasonable and Necessary Standard; Components of Showing of Efficacy

Neither ALJ Jones or ALJ Steele appeared to take any issue with the assay's high degree of predictability for screening drugs to which an individual patient is "resistant" (likely to be

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21. (...continued)
most effective on the assay").

22. A.R. at 7220.

23. Cf. A.R. at 1599 (ALJ Cummings' observation that the communications from these doctors were nonetheless "somewhat inconsistent" with the July, 2000 letter); *supra* at 6.

24. Cf. Plaintiff's MLSMSJ at 25 (observing that notes relied on by ALJ Steele contain no information regarding credentials, basis for conclusions, or physicians' review/familiarity with literature/published research). Cf. also Medicare Program Integrity Manual § 13.7.1 (explaining that consensus of recognized authorities in specific field is relevant evidence of medical acceptance).

unresponsive), although both noted its lesser predictability for potential chemotherapy drugs at the other end of the spectrum - "sensitive" (those likely to be most responsive). Cf. *supra* n. 2 (noting reciprocal nature of labels). And in determining that the assay did not qualify as a "reasonable and necessary" medical expense entitled to reimbursement under the Act, each ALJ (1) concluded that treating physicians would not alter their course of treatment for cancer patients from the general clinical protocol solely/conclusively on the basis of individualized response information from the assay (*i.e.*, that the assay confers no treatment benefit); and (2) relied on the ASCO Assessment, which looked to survival outcome as the sole measure of outcome benefit.[25]

Plaintiff objects to what it characterizes as the ALJs'/MAC's imposition of requirements "well beyond the 'reasonable and necessary' standard", see, *e.g.*, Plaintiff's Reply in Support at 3, while Defendant responds that the Secretary "has broad authority to explicate . . . what is considered 'reasonable and necessary' in case-specific adjudications", see Defendant's Reply at 4. This Court simply concludes that the ALJs' decisions are not grounded on substantial evidence within the requirements of this Circuit. That is, the ALJs' omissions and/or unfounded/unsubstantiated assumptions in application of the "reasonable and necessary" standard necessitate remand.

(a) Different Course of Treatment

25. Cf. Defendant's Reply at 2 n. 2 (noting Defense counsel's expression during status conference that testing "should result in a treatment regimen that is 'different and better' than the protocol already prescribed through clinical trials" but describing ALJ opinions as "more oblique on this point").

As discussed at length *supra*, the Decisions provide essentially no explanation for the ALJs' (i) rejection of significant competent medical evidence (including that of treating physicians, experts, and a former CMS/HCFA Coverage Director) of the utility of the assay as a

significant factor in a multi-factor evaluation of potential chemotherapy treatments, in favor of (ii) a presumption that the assay results are without utility because they do not/would not in practice wholly supplant established protocols.[26]

The clinical utility of a test may be judged by how it influences patient care. It was incumbent upon the ALJs, however, to explain their rejection of the opinions of numerous highly-credentialed practicing oncologists and academicians/researchers that reliance on empirical studies and standard protocols alone is no longer the best diagnostic option given the proliferation of treatment options and the availability and predictability of this generation of chemotherapy assays.[27] Compare A.R. at 1565 (ALJ Cummings Decision, concluding that

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26. The Administrative Record suggests that a definition of "reasonable and necessary" which excluded assay testing from Medicare coverage because the physician *could* make a treatment decision without it (*i.e.*, on the basis of clinical protocols), would be in tension with Medicare coverage for other diagnostic tests performed to *inform* patient care, *i.e.* to obtain additional information necessary to the physician's evaluation of the most appropriate treatment.

27. See, *e.g.*, A.R. at 692-695 (Declaration of Dr. Edward Weiser, gynecologic oncology specialist, Emory University School of Medicine, noting that he uses the assay in practice when chemotherapy is an option for his cancer patients; that utilizing assay, rather than basing drug choice on clinical trial results alone, allows him to take into account individual patient differences, which can have an effect on treatment and improve the level of care; and that it is reasonable and necessary for primary as well as recurrent tumors because of its predictive value); id. at 694 (also explaining that the assays are "well known and accepted in the medical community as a useful clinical tool for individualizing cancer therapy"); A.R. at 1134 (quoting evidence of Dr. Matthew Powell, Washington University School of Medicine oncologist, that assays are "an invaluable tool in assisting [him] with making treatment decisions [for his cancer patients]); id. ("I consider the patient-specific information provided by the assay, in conjunction with the patient's clinical picture and any standard empiric treatment protocols that may exist for the type and stage of cancer involved, to determine the best treatment option . . . The benefits of treating in conjunction with information gained from the . . . assays are numerous."); Cf. A.R. at 7275 (Transcript of testimony before MCAC panel by Dr. William Grace, former Chief of Cancer Research and Medical Oncology at St. Vincent's, describing strides in treatment of pancreatic cancer in New York City practice utilizing assays to "tell us what combinations [of chemotherapy agents] to use" rather than repeatedly trying different standard protocols which (continued...)

"[c]linical laboratory tests should be medically necessary when the physicians who ask for them have a valid medical reason for doing so" and "requirement that documentation be shown to establish that tests were effectively used" was unreasonable).

The ALJs have provided little explanation for either (i) a presumption that treating physicians/oncologists requesting the assay and certifying to its medical necessity would then deviate from what would, in their opinion, be the best course of treatment, owing to legal liability considerations[28] or (ii) a conclusion that physicians would not deviate from standard

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27. (...continued)
can "essentially chemo patients to death").

See also id. at 693 (explaining that patients with recurrent tumors are"frequently in poor physical health secondary to disease progression and the cumulative effects of prior chemotherapy", so it is helpful to have assay results available when it later becomes difficult or impossible to get a specimen); A.R. at 690 (Affidavit of Dr. Stark-Vance, explaining that she attempts to obtain an assay specimen for patients for whom chemotherapy is a treatment option because "it is often difficult to get a specimen later" and "many patients do not want to undergo a second surgery to obtain a specimen"). These constraints on a physician's ability to obtain a tissue sample for assay later in a patient's disease progression were not addressed by ALJ Jones in the course of his conclusion that testing should generally be covered only when a cancer is recurrent.

28. The Administrative Record encompasses significant physician/oncologist evidence that this generation of assay affords them valued opportunities to maximize the patient's response to highly toxic/debilitating treatment, and avoid unnecessary adverse effects of likely ineffectual courses of chemotherapy.(*e.g.*, toxicity and related weakness, further degeneration, delays in effective treatment and related continued progression of the cancer, and loss of quality/family time). See, *e.g.*, A.R. at 690 (Declaration of Dr. Stark-Vance, observing that "[a]ny doctor who is trying to come up with the best treatment plan for his or her patient, is trying to find something that will increase the odds of treatment success and reduce the odds of additional toxicity from ineffective treatment").

protocols, premised on studies not designed to encompass/measure that question[29] and/or one written and two oral responses of three (3) largely unidentified physicians.

Finally, ALJ Jones' presumption that treating physicians would not vary an initial cancer patient's treatment from the standard protocol for fear of liability for deviation from the "standard of care" is at odds with both (a) extensive evidence of record regarding the proliferation of treatment options that may be comparably effective and (b) the fundamental nature of a standard of care. More specifically, a medical standard of care is necessarily fluid/evolving, and informed by physicians' clinical judgments of what best serves their patients. Cf. A.R. at 695 (Declaration of Dr. Weister, noting that "a new technology need not be the 'standard of care' . . . to be acceptable to a medical community" and the "medical community recognizes the value of having a diversity of medical treatment approaches").

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29. See A.R. at 7871 (ASCO Assessment addressing question of whether "assay-guided therapy affect[s] the choice of chemotherapy agent" by acknowledging importance of "how often performance of the assay makes a difference for the patient" and concluding that "[t]his type of information, however, is unavailable in the published literature on the [assays] and is not easily obtained"). Compare, *e.g.*, A.R. at 691 (January, 2006 Declaration of Dr. Stark-Vance, describing her use of assay as a "guide" in selecting and deselecting chemotherapeutic drugs, and describing failure to consider physician's integration of assay results in clinical decision-making as "affect[ing] the validity of the [ASCO] assessment"); A.R. at 694 (January, 2006 Declaration of Dr. Weiser, noting that ASCO assessment "asked oncologists whether they would treat based on assay results alone [when] in fact oncologists use chemoresponse assay as one factor in making a determination"); cf. A.R. at 1133 (PTI Evaluation and Response to BCBSA Technical Assessment, observing that it "assumed" assay testing was to be a "replacement for empiric data"). Cf. also, *e.g.*, A.R. at 742 (Letter of Aaron Amos, M.D., Texas urologist, indicating that he utilizes the assay for renal cell cancer patients with advanced disease; it is a treatment factor, together with the patient's general health, disease status, and the toxicity of available alternatives; and it can greatly facilitate treatment); *supra* (noting ALJ Jones' acknowledgment of importance of consideration of side effects in selecting treatment).

(b) Improved Outcome (or Benefit to Patient)

As also discussed at length above, the Decisions provide little or no explanation for their (a) rejection of significant medical evidence of benefit to initial and recurrent cancer patients in the form of both longer progression-free intervals and the avoidance of ineffective toxicity and potential further health degradation from courses of chemotherapy unlikely to be effective, in favor of (b) evidence narrowly defining patient benefit as an improvement in survival outcome.[30] Cf. Defendant's MSSJ at 19 n. 9 (noting that Medicare Coverage Advisory Committee panel voted that "clinical response as well as survival rate" was appropriate measure of clinical utility) (citing A.R. at 7263); A.R. at 1546-47 (similarly noting that in November, 1999, the Medicare Coverage Advisory Committee's Laboratory and Diagnostic Services Panel concluded that clinical response as well as survival rates should be accepted as an appropriate measure of clinical utility);[31] id. at 1549 (citing Scientific American Cancer Journal, May 1999 article discussing "elimination of ineffective treatments, needless toxicity, and loss of quality of life" in evaluating "cost-effectiveness of assay-directed therapy compared with conventional therapy"); id. at 1607 (noting that at Public Hearings in 1999, Dr. Bagley, as Director of Coverage at

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30. Compare, *e.g.*, IJGC Study- Institutional Review Board ("IRB") approved retrospective study of effectiveness of assay-directed therapy measured by progression-free interval ("PFI") and observing a two to three-fold increase in PFI "in patients who received a drug(s) to which their tumor was assayed to be sensitive compared to those who were treated with agents deemed to be resistant" with ASCO/BCBSA recommendations that assessment of survival benefit be basis for clinical adoption of assays. Cf. A.R. at 691 (Declaration of Dr. Stark-Vance indicating that most of her brain tumor patients, with assay guided management, have lived between 2-3 years, compared to a general life expectancy of 8-12 months); A.R. at 1655 (Correspondence of Dr. Joseph Buell, University of Cincinnati Surgeons, who utilizes assay for colorectal, gallbladder, liver and kidney cancers, citing 1991 study demonstrating improved survival rate of gastric and colorectal cancer patients treated with assay-identified effective drugs).

31. See also A.R. 7252-7265 (Meeting Minutes of November 15-19, 1999 Panel).

CMS/HCFA advised that in considering the value of chemotherapy assays, the question was not limited to whether "the use of the assay will result in better survival rates" but also whether "the patient has an improved quality of life"). Cf. also ALJ Jones Decision at 12 ("Patients with tumors treated primarily by chemotherapy are unlikely to become disease free under any circumstances. . . . the percentage of successful chemotherapy treatments . . . is generally below 30%. The realistic goal of most chemotherapy is to produce a period of remission and possibly extend the patient's life expectancy.").[32]

Most simply, the Administrative Record indicates that patients are harmed by chemotherapy with ineffective drugs - that it has physical, emotional, and financial costs - and that they benefit in these same ways from efficiencies in their cancer treatments.[33] The treating physicians from whom PTI provided evidence repeatedly represent that factors such as their cancer patient's health and disease progression, the reliability/success rates of the clinical protocols, and the number and degree of toxicity of the various chemotherapy alternatives inform their decisions to request, as "medically necessary", the additional treatment information that assay testing can provide.[34] Yet the ALJs implicitly appeared to accord no value to cancer

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32. Compare Id. at 6 (noting that "focus of treatment for [ovarian cancer] is less about lengthening life expectancy than on enhancing the quality of life by avoiding as many of the unpleasant side-effects, and high costs, of chemotherapy as possible"); *supra* at 7 (noting that carrier began providing assay coverage for gynecologic cancers post- 2004).

33. See, *e.g.*, A.R. at 743 (Declaration of Dr. McCarthy, observing that "ineffective treatment results in unnecessary toxicity, loss of treatment time, may make the patient resistant to a drug that may have been effective, financial cost, and emotional cost").

34. See, *e.g.*, A.R. at 746 (Declaration of Peter D. Beitsch, M.D., Texas oncologist, who writes, as an example, that he ordered the assay for a patient with aggressive lung cancer that "has variable responsiveness to chemotherapy with a considerable amount of toxicity").

patients' quality of remaining life or increase in progression-free intervals in reaching their conclusion that the assay is not "reasonable and necessary".

III. Conclusion

In sum, the Administrative Record underlying these Decisions reflects significant evidence that physicians/oncologists utilize the assay for initial/primary and recurrent cancer patients; that treating physicians regard the assay as medically necessary in selecting among potential chemotherapy regimes and identifying the best course of treatment for the individual cancer patients for whom it is requested; that physicians/oncologists indicate that they would, and do, deviate from the standard protocols in the course of decision-making that includes assay results as an important factor; and that studies document, and physician/oncologists attest to observing in their practices, patient benefits to assay-guided therapy in the forms of, *e.g.*, avoidance of ineffective chemotherapy and extended progression-free intervals. And as discussed at length above, the ALJs' decisions failed to meaningfully engage/address much of this contrary probative evidence and/or rested on unsubstantiated assumptions. For these reasons, it is recommended that Defendant's Motion for Summary Judgment be denied, that Plaintiff's Motion for Summary Judgment be granted except as to its request for costs and fees, and that these Decisions of the Secretary be remanded to the ALJs for further consideration.

In accordance with the Magistrate Judges Act, 28 U.S.C. § 636(b)(1)(B) and (C), and Rule 72.D.2 of the Local Rules of Court, the parties are allowed fourteen (14) days from the date of service of a copy of this Report and Recommendation to file objections. Any party opposing

the objections shall have fourteen (14) days from the date of service of objections to respond thereto. Failure to file timely objections may constitute a waiver of any appellate rights.

Respectfully submitted,

LISA PUPO LENIHAN
United States Magistrate Judge

Dated: June 25, 2010